IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	Group Art Unit: 3739
Albert K. Chin	Examiner: Smith, Philip Robert
Serial No.: 10/696,381	Confirmation No.: 8269
Filed: October 28, 2003	
For: LONGITUDINAL DILATOR	

NOTICE OF APPEAL &
REQUEST FOR PRE-APPEAL BRIEF CONFERENCE

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Advisory Action mailed January 28, 2010, Applicant herein submits a Notice of Appeal pursuant to 37 C.F.R. §41.31(a), and requests for a pre-appeal brief conference.

I. Claim Rejections under 35 U.S.C. § 112

Claims 27-35 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. According to the Office Action, the specification does not describe an outer sheath that has a distal tip for dissecting tissue, as described in claim 27. Applicant respectfully notes that at least figures 5 and 6, and their corresponding description (e.g., paragraphs 15, 16) describes embodiments of an outer sheath that has a distal tip for dissecting tissue. Thus, Applicant respectfully submits that claim 27 should satisfy § 112.

Claim 29 recites that the distal tip is fixedly secured to a distal end of the outer sheath. Support for these limitations can be found at least in figures 5 and 6, which illustrate the distal tip being secured to the distal end of the outer sheath to thereby fix the position of the distal tip relative to the outer sheath. Thus, claim 29 should satisfy § 112.

Claim 31 recites that the expansion device is housed within a lumen of the outer sheath, and is prevented from moving distal to the distal tip of the outer sheath. Support for these

limitations can be found at least in figures 5 and 6, which show that the expansion device within the outer sheath is proximal to the distal tip, and cannot be moved past the distal tip (because the distal tip has a closed end). Thus, claim 31 should satisfy § 112.

According to the Advisory Action, claims 27-35 should be withdrawn. However, Applicant respectfully notes that claims 27-35 have been examined, as evidenced by the § 112 rejections and § 103 rejections set forth in the last Office Action for these claims. The request for withdrawal of these claims in the Advisory Action is thus untimely, especially when these claims are now in the appeal process.

II. Claim Rejections under 35 U.S.C. § 103

Claims 15, 21-23, 25-31, and 34-35 stand rejected under 35 U.S.C. § 103 as allegedly being unpatentable over U.S. 5,318,588 (Horzewski) in view of U.S. 6,264,670 (Chin).

Claim 15

A. Horzewski does not disclose or suggest a distal tip configured to dissect tissue.

Claim 15 recites an elongated instrument having *a distal tip configured to dissect tissue* (Emphasis Added). According to the Office Action, Horzewski allegedly discloses a distal tip 127 configured to dissect tissue. However, Applicant respectfully notes that the element 127 of Horzewski is a "bulbous region" that is configured to expand an outer sheath (column 12, line 63 to column 13, line 18). There is nothing in Horzewski that discloses or suggests that the bulbous region is configured to dissect tissue, as described in claim 15.

According to the Advisory Action, the element 127 of Horzewski is "capable" of dissecting tissue because it has a "leading taper." However, Applicant respectfully submits that just because the device has a tapered configuration, it does not automatically make the device suitable for dissecting tissue. Notably, the tapered portion of the element 127 ends at a substantially *flat* distal tip. Thus, the element 127 of Horzewski is in fact not capable of dissecting tissue. There is nothing in Horzewski that disclose or suggest that the element 127 is for dissecting tissue, and the substantially flat distal tip of the element 127 in fact makes it incapable of dissecting tissue.

B. Providing viewing cannot be the proper motivation for the purported combination of references.

Claim 15 also recites that the distal tip is transparent. According to the Office Action, Chin discloses a transparent tip, and it would have been allegedly obvious to provide the

transparent tip of Chin for the device of Horzewski. Applicant respectfully traverses. As discussed in Applicant's last response, the device of Horzewski already has a through lumen with a distal opening, which could already provide viewing by an endoscope. Since the device of Horzewski is already capable of providing viewing, the purported reason of providing viewing cannot be the motivation to make the bulbous region 127 transparent.

According to the Advisory Action, making the bulbous region 127 transparent would provide "more viewing." Applicant respectfully disagrees. In the device of Horzewski, if any more viewing is needed, the endoscope can simply be extended out of the distal opening of the central lumen of Horzewski. Therefore, contrary to the Examiner's argument, the device of Horzewski is already capable of providing full scope viewing by an endoscope, and as such, providing viewing cannot be the proper motivation for the purported combination.

C. The purported modification of Horzewski would render Horzewski's device inoperable.

Also, to the extent that it is suggested in the Office Action that the transparent tip of Chin be used to replace the bulbous region 127, Applicant respectfully notes that such purported modification would render the device of Horzewski inoperable. This is because Horzewski teaches a device with a through lumen so that a guidewire can extend therethrough (column 10, lines 30-36; column 12, lines 46-55). Placing the tip of Chin on Horzewski's device would prevent the guidewire from extending though the sheath. Also, the device of Horzewski requires the bulbous region 127 to have an expansion taper 124 (column 12, lines 65-68), so that withdrawal of the bulbous region 127 can cause an expansion of the outer sheath via the taper 124. The tip of Chin cannot achieve such function. Thus, the purported modification of the device of Horzewski would contradict the teaching of Horzewski, and would render the device of Horzewski inoperable for its intended purpose. Note that a prima facie case of a § 103 rejection cannot be established if a purported modification would render a device in a reference operable, or if it contradicts a teaching of a reference.

In the Advisory Action, the Examiner seems to agree with Applicant's above argument. However, the Examiner indicates that Horzewski discloses other devices that are not used with guidewire, making the argument that the purported combination would not render these other devices inoperable. Applicant must respectfully disagree. Horzewski's "invention. . . relates to tubular components or channels of medical devices that function to accommodate guidewires" (column 1, lines 19-21). Thus, while Horzewski states that the scope of invention is not limited

to the particular application, it is clear from the entire disclosure of Horzewski that any other device in other applications would also involve use of a guidewire.

Also, according to the Advisory Action, the Examiner argued (for the first time) that an alternative basis of an obviousness rejection is to just combine the transparent material from the device of Chin, and use the transparent material to construct the tip of Horzewski, so that the device of Horzewski could accommodate a guidewire. However, Applicant respectfully submits that it is improper to selectively choose different features from different references only for the purpose of assembling a set of features to meet the claimed elements. Rather, the entirety of the cited references must be considered. In this case, Horzewski specifically teaches that the device with the elongated cannula body 150 and the distal section 127 be constructed from the same material to provide a unity configuration (note the hatched cross section shown in figure 6B). Thus, in view such disclosure of Horzewski, and in view of the fact that the device of Horzewski is already capable of providing full scope viewing by an endoscope, one skilled in the art would not be motivated to construct just the distal section 127 of Horzewski with a transparent material, as purported in the Office Action.

For at least the foregoing reasons, claim 15 and its dependent claims should be allowable over Horzewski, Chin, and their combination.

Claim 27

Claim 27 recites an apparatus that includes an elongated instrument having an expansion device, and an outer sheath disposed about at least a portion of the elongated instrument, the outer sheath having a distal tip for dissecting tissue. Horzewski and Chin do not disclose or suggest the combination of the above limitations. Rather, Horzewski discloses a dilator 150 with a bulbous region 127 (figure 6B), with a sheath 90 surrounding the dilator 150 (figure 5A). Notably, to the extent that the bulbous region 127 of Horzewski is analogized as the claimed distal tip, the bulbous region 127 is a part of the dilator 150, not the sheath 90. Thus, Horzewski clearly does not disclose or suggest an outer sheath having a distal tip for dissecting tissue, as described in claim 27. Chin also does not disclose or suggest the combination of the above limitations, and therefore fails to make up the deficiencies present in Horzewski. Since both Horzewski and Chin do not disclose or suggest the combination of the above limitations, any purported combination of these references cannot result in the subject matter of claim 27.

Also, Applicant notes that the Office Action has not specified which elements of claim 27 are purported to be met by which elements in the Horzewski and Chin references. Thus, to the extent that the Examiner is inclined to maintain the § 103 rejections for claim 27, Applicant respectfully requests that the Examiner indicate which elements from the cited references are being analogized as the claimed features.

Furthermore, to the extent that the Office Action appears to suggest that the tip of Chin be used to replace the bulbous region 127 (which the Examiner analogized as the claimed "tip") of Horzewski, Applicant submits that there is no proper motivation for such purported modification, and such purported modification would render the device of Horzewski inoperable, as discussed. For at least the foregoing reasons, claim 27 and its dependent claims should be allowable over Horzewski, Chin, and their combination.

The Commissioner is authorized to charge any fees due in connection with the filing of this document to Vista IP Law Group's Deposit Account No. **50-1105**, referencing billing number **MAQ 06-00741US05**.

Respectfully submitted,

DATE: March 5, 2010

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